

REMARKS

Applicant thanks the Office for the Examiner's Interview conducted on May 10, 2011. In response to the Interview Summary mailed May 13, 2011, Applicant notes that no agreement was reached with respect to the claims and agrees with the Substance of the Interview provided in the Summary.

A. Amendments to Claims.

Claims 1 and 12 are amended to clarify that the agent having ectoparasiticidal activity of the invention consists essentially of isopropyl myristate in a concentration between 10 and 70% w/w of the composition to be used according to the claims. No new subject matter is added by the amendments, which merely restate and emphasize the "sole ectoparasiticidal agent" limitations deleted from the claims.

B. Governing Law.

As set forth at MPEP 2143:

"The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. [citations omitted] "[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." KSR, 550 U.S. at ___, 82 USPQ2d at 1396.

If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art."

In determining obviousness, the point is not whether the skilled person *could* have arrived at the invention by adapting or modifying the closest prior art, but whether the prior art provides a reasonable expectation that doing so would solve an objective technical problem or produce an improvement. In that respect, a prior art reference must be considered in its entirety, i.e., *including* those portions that lead away from the claimed invention (*W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)).

C. Response to Rejections under Section 103(a), based on Singer U.S. Patent No. 4,147,800.

1. Response to rejection of claims 12-15.

The Office Action asserts that Singer teaches the use of isopropyl myristate (IPM) to kill ectoparasites at a concentration of 70% “with death in a two minute test,” with reference to Curve 2 of Figure 1. The Action acknowledges that the test composition whose activity is reflected in Figure 1 includes polysorbate (specifically, polysorbate 80; Singer, Col. 4, lines 21-26). Nonetheless, the Action contends that the composition represents one in which no other ectoparasiticidal agents are present, as claimed.

Applicant respectfully disagrees. Firstly, polysorbate 80 is one of the chemicals whose use in the present invention is explicitly discouraged (Specification at page 11, line 20). It is excluded from the present claims as an agent with ectoparasiticidal activity.

In that regard, polysorbate 80 is a fatty acid ester (monooleate) of sorbitol (co-polymerized with ethylene oxide), or polyoxyethylene sorbitan monooleate. It is highly soluble in water, which was also present in the test compositions of Singer (*ibid.*, at lines 22-23). Monooleate is one of the “aliphatic monoesters containing 4 to 28 carbon atoms”, described by Singer as “potent pediculocides” (Col. 5, lines 21-23). Thus, the test composition whose activity is referenced in Curve 2 of the Figure cited in the Office

Action contained not one but *two* fatty acid ester components described by Singer as possessing potential pediculocidal activity. The pediculocidal component of the composition therefore did not consist essentially of isopropyl myristate, as presently claimed.

Further, Singer *teaches away* from use of isopropyl myristate alone as an ectoparasiticidal, for all the reasons of record. In particular, Singer explicitly teaches that IPM alone below the purportedly toxic level of 70% w/w (Col. 2, lines 55-57) is described as being *ineffective* to kill 100% of lice as presently claimed (see, Col. 4, lines 31-32, emphasis added):

“it required not less than 70% of the isopropyl myristate [*even in combination with the polysorbate 80 and water*] to achieve a 100% mortality.”

Therefore, rather than use isopropyl myristate as presently claimed, Singer requires an “admixture of an aliphatic or aryl aliphatic alcohol” with an aliphatic ester (see, e.g., the Abstract, Col. 1 line 61 through Col. 2, line 9, and Col. 3, lines 60- Col. 4, line 37). Nothing in the reference teaches use of isopropyl myristate as the only ectoparasiticidal agent present. To the contrary, the Figure cited in the Office Action to support that contention was provided by Singer to prove the *opposite* point; i.e., that it took concentrations of isopropyl myristate greater than the 70% presently claimed to kill ectoparasites (Col. 4, lines 31-32), such that 100% mortality could only be “achieved in this two minute test when the isopropyl alcohol concentration reached 30%.” (Col. 4, lines 35-37).

According to Singer, aliphatic alcohols are active ectoparasiticides (see, e.g., Curve 3 of the Figure, Table II, Table V, and Col. 1 line 61 through Col. 2, line 9). Their use is therefore precluded in the present invention for two reasons: (1) the claims exclude use of

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alcohols generally; and (2) the claims exclude use of an ectoparasiticidal agent other than isopropyl myristate.

In summary, nothing in the Singer reference provides the art with any teaching or suggestion for use of isopropyl myristate as the sole ectoparasiticidal agent. To the contrary, the data relied upon in the Office Action as teaching use of IPM alone (Curve 2 of the Figure) actually demonstrates use of IPM with *another* active agent whose use is excluded by the present claims. Even then, Singer explicitly teaches away from use of isopropyl myristate as an active agent at a concentration lower than 70%, as presently claimed. All other use of IPM mentioned in Singer is as a component of a composition with another ectoparasiticide, an aliphatic alcohol, whose use is excluded by the present claims.

The law does not allow one to read the prior art in a way that would contradict its basic teachings, or to disregard the portions of the art which lead away from a claimed invention. However, even if one did ignore not only Singer's requirement for use of an alcohol, but also its teachings regarding the use of other monoesters (as in polysorbate 80) and its conclusions that IPM is only effective at concentrations above 70%, one could still not have a reasonable expectation that the remaining composition would, as claimed, be capable of killing ectoparasites within an hour following a 10 minute or less application.

For its conclusion to the contrary, the Office Action points again to the data in Curve 2 of the Figure in Singer, referencing a kill rate of 82-100% in a two minute test. However, the two minute test was an immersion test, not a topical one as presently required. Moreover, it was performed using more than one agent identified by Singer as having ectoparasiticidal activity (the 18 carbon monooleate monoester). Further, the reference teaches that the kill rate achieved did not occur for **24 hours** (Col. 3, lines 23-26), far longer than the **one hour** to death achievable and required by the present invention.

For all of the reasons stated, the Singer reference cannot be read to suggest use of IPM as a sole active agent when it does not do so and, in fact, takes pains to suggest otherwise. Nor can Singer be read to teach or suggest a composition having IPM in the concentrations required by the present claims, nor that such a composition would have the killing efficacy also required by the claims.

Reconsideration and withdrawal of the rejection of Claims 12-15 based on Singer under Section 103 is therefore respectfully requested.

2. Response to rejection of Claims 1-4 and 32.

For all of the reasons discussed above, the teachings of the Singer reference are inapposite to claims 1-4 and 32 as much as they are to claims 12-15 discussed above.

As to the additional limitation on claims 1-4 and 32 specifically excluding use of any alcohol from the composition of the invention, the Office Action asserts that one could simply leave the alcohol of Singer out of the Singer composition “if subject is sensitive.” (Action at page 2).

However, doing so would be entirely contrary to the teachings of Singer. As discussed above, Singer explicitly teaches that one must use an aliphatic alcohol—no one reading the reference could reasonably conclude that the alcohol is optional. Moreover, were one to nonetheless ignore Singer’s requirement for use of an alcohol, the only remaining guidance in Singer points to a composition containing either greater than 70% IPM (Col. 2, lines 53-55) and/or one containing another active (Col. 3, lines 61-65 and Curve 2 of the Figure). Neither composition would fulfill the requirements of the present claims, which require less than 70% IPM in a composition containing no other ectoparasiticidal agent.

Further, as noted elsewhere above, were one to not only ignore Singer's requirement for use of an alcohol, but also its teachings regarding the use of other monoesters (as in polysorbate 80) and its conclusions that IPM is only effective at concentrations above 70%, one would still not have a reasonable expectation that the remaining composition would, as claimed, be capable of killing ectoparasites within an hour following a 10 minute or less application.

Therefore, the relied upon data in Singer does not support the conclusion stated in the Office Action that the kill rate required by the claims is taught by the reference. Based on all the foregoing, Applicants submit that the invention of claims 1-4 and 32 is not obvious over Singer. Reconsideration and withdrawal of the rejection of claims 1-4 and 32 is therefore respectfully requested.

D. Response to Rejection of Claims 12-16 and 32 (Singer in view of Reid US Patent No. 5,972,987, further in view of Von Bittera US Patent No. 4,544,547.

Singer is cited for the reasons discussed above, with the exception of combing, which is not taught. Reid is cited for use of a comb to remove killed lice. Von Bittera is cited for its Example 2, which is mistakenly described as showing use of IPM in the control of ectoparasites.

As previously noted, Singer does not render the invention obvious. The von Bittera reference adds nothing of substance to the rejection. It merely describes a conventional use of IPM as a spreading agent, similar to its use in many beauty products which neither possess nor claim ectoparasiticidal activity (see, e.g., Col. 9, lines 9-37). As a spreading agent, concentrations of IPM are suggested for use in von Bittera that fall below the concentrations required by the present claims (*ibid*, at lines 36-39). As such, the reference lacks any suggestion or teaching for ectoparasiticidal use of IPM.

Nonetheless, the Office Action dismisses the absence of such teaching in von Bittera as merely requiring modification of ingredient parameters to achieve a known effect.

However, to support an obviousness rejection, the art must teach or suggest all of the claimed elements *without changing their function*.

What is claimed is use of a composition to kill ectoparasites within an hour by topical application of a composition in which the ectoparasiticide consists essentially of IPM.

What von Bittera teaches is killing ectoparasites with insecticides (see, e.g., Col. 3, lines 22-49, ectoparasitidal agents to be used in von Bittera's invention are either carbamates or pyrethroids). In von Bittera, IPM is an incidental inactive ingredient, present in amounts far less than those required by the present claims. It does not serve the function presently claimed.

To arrive at the present invention from the cited art, one would have to eliminate the actives required by Singer (alcohols) and von Bittera (insecticides), and use IPM in amounts not suggested by von Bittera and explicitly discouraged by Singer. Then, with no guidance from any of the references, one would have to guess that IPM could, at the concentration claimed, not only kill ectoparasites but do so at least 23 hours faster than Singer demonstrated using IPM with other actives.

The Office Action characterizes the claimed result as a "result effective parameter" that would be obvious to vary. However, to be obvious, a particular parameter must first be *recognized* as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation (see, *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977), and MPEP 2144.05). Here, the fact that IPM alone could, at the concentrations claimed, not only kill ectoparasites but do so within an hour is not suggested anywhere in the cited art.

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In other words, one could not merely adjust a few variables to reach a result that one does not know can be achieved. Nothing in the cited art provides a reasonable expectation or, indeed, any expectation of success with an invention having all the elements required by the claims (and none excluded by them). It is respectfully submitted that a contrary conclusion requires a strained reading of the prior art that is in many respects directly at odds with what the references actually teach.

Reconsideration and withdrawal of the rejection of claims 12-16 and 32 is therefore respectfully requested.

CONCLUSION

All of the pending claims (1-4, 12-16, 19, 21, and 32) are believed to be in condition for allowance. Favorable action thereon is therefore respectfully requested.

The Commissioner is hereby authorized to charge the total amount of \$960.00 to cover the Request for Continued Examination fee (\$405.00) and the Three Months Extension of Time fee (\$555.00) to Deposit Account 07-1896. The Commissioner is also authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment thereof, to Deposit Account No. 07-1896, referencing the above-identified docket number.

Respectfully submitted,

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